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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,190	11/13/2001	Kazutoh Takesako	1422-0502P	6479

2292 7590 11/03/2004
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EXAMINER
BASKAR, PADMAVATHI

ART UNIT 1645	PAPER NUMBER
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DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/987,190

Applicant(s)

TAKESAKO ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5 and 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/11/04 has been entered.

Amendment

2. Applicants amendment filed on 7/7/04 is acknowledged and entered.

Status of Claims

3. Claims 4 and 6 have been amended.

Claim 21 is canceled.

Claims 4 and 6 are under examination.

Claims 1-3, 5 and 7-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

4. In view of the amendment to the claim, the rejections of record in the previous office have been withdrawn and the following First Action on Merits is issued for the claims 4 and 6 (RCE) filed on 8/11/04.

Priority

5. This application is a divisional of U.S. Serial No. 09/262,856, filed March 4, 1999, now U.S. Patent No. 6,333,164, which is a continuation-in-part application of PCT/JP97/0304I. The priority for the present claims will be accorded as of the filing date of the Parent application 09/262,856 (U.S. Patent 6,333,164) filed on 3/4/1999 as there is no support found for isolated nucleic acid in PCT/JP97/0304I, 8/29/1997.

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Claim Rejections - 35 USC 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

Claim 4 is drawn to an isolated nucleic acid encoding a fungal antigen comprising an antigenic protein having a vaccine activity or an allergen activity originating from *Candida albicans*, wherein said antigenic protein comprises the partial amino acid sequence as shown by SEQ ID NO: 2 in Sequence Listing and has a molecular weight of about 25,000 Daltons as determined by SDS-PAGE under reduced conditions.

Claim 6 is drawn to an isolated nucleic acid encoding a fungal antigen which originates from the genus *Candida* and has a molecular weight of about 25,000 Daltons and has a vaccine activity or an allergen activity, wherein said nucleic acid hybridizes to a nucleic acid which encodes a fungal antigen comprising an antigenic protein having a vaccine activity or an allergen activity originating from *Candida albicans* in 6X SSC, wherein 1 x SSC indicates 0.15 M NaCl, 0.015 M sodium citrate, and PH 7.0, containing 0.5% SDS, 0.1% bovine serum albumin (BSA), 0.1% polyvinyl pyrrolidone, 0.1% Ficoll 400, and 0.01% denatured salmon sperm DNA at 50°C; followed by washing initially at 37°C in 2X SSC containing 0.5% SDS and changing the SSC concentration to 0.1X SSC and the SSC temperature to 50°C, wherein said antigenic protein comprises the partial amino acid sequence as shown by SEQ ID NO: 2 in Sequence Listing and has a molecular weight of about 25,000 Daltons as determined by SDS-PAGE under reduced conditions.

The claim 4 encompasses an isolated nucleic acid encoding a fungal antigen comprising an antigenic protein comprising the partial amino acid sequence as shown by SEQ ID NO: 2 from *Candida albicans* and has a molecular weight of about 25,000 as determined by SDS-

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PAGE under reduced conditions and claim 6 recites any isolated DNA encoding a fungal antigen comprising an antigenic protein comprising the partial amino acid sequence as shown by SEQ ID NO: 2 from genus *Candida* which includes *Candida galli*, *Candida asparagi*, *Candida diospyri*, *Candida qinlingensis*, *C. tropicalis* and *C. glabrata* and *Candida albicans* etc which would hybridize thereto under moderate conditions to an isolated nucleic acid encoding a fungal antigen comprising an antigenic protein comprising the partial amino acid sequence as shown by SEQ ID NO: 2 from *Candida albicans*. Review of the present specification and the sequences of record for claimed isolated nucleic acid indicates that such an isolated nucleic acid has not been identified or described. Presently, in order to practice the invention as claimed the artisan must first obtain the claimed isolated nucleic acid encoding a fungal antigen comprising the partial amino acid sequence as shown by SEQ ID NO: 2 and has a molecular weight of about 25,000 daltons. However, the present specification does not teach the structure of the claimed nucleic acid. Moreover, the specification fails to describe any other representative species (*Candida galli*, *Candida asparagi*, *Candida diospyri*, *Candida qinlingensis*, *C. tropicalis* and *C. glabrata*) of genus *Candida* by any identifying characteristics or properties other than the functionality of encoding fungal antigen. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

8. Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims have been described supra.

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The specification (pages 96-98) describes as a part of invention *C. albicans* 25kD protein in a solubilized fraction by using solublizer from the insoluble fractions from fungal cells of which cell wall has substantially removed or partially purified and comprises the N-terminal amino acid sequence as shown by SEQ ID NO: 2. However, the specification fails to disclose the same *C. albicans* 25kD protein comprising the partial amino acid sequence SEQ.ID.NO: 2, KYSLPELDYEFSAPEPYISGQINEIXYT Or a cDNA sequence (having start and stop codons) from *C. albicans* that encodes a fungal antigen comprising the partial amino acid sequence as shown by SEQ ID NO: 2, KYSLPELDYEFSAPEPYISGQINEIXYT or the claimed protein from other representative species of *Candida galli*, *Candida asparagi*, *Candida diospyri*, *Candida qinlingensis*, *C. tropicalis* and *C. glabrata*. The specification fails to provide any detail on an isolated nucleic acid encoding 25kD fungal antigen comprising the partial amino acid sequence SEQ.ID.NO: 2. In the instant case, the claimed embodiments of the polynucleotide sequence are needed to make use of the invention as claimed. To decide whether a specification is enabling, it is to be determined whether the specification discloses sufficient guidelines for successful making and using of the claimed invention without undue experimentation. As described above, the specification fails to provide sufficient guidelines for a skilled artist to have practiced the invention as claimed without undue experimentation because the specification does not provide sufficient guidance for making and using the invention as claimed. Therefore, Claims 4 and 6 are also rejected under 35 U.S.C. 112, first paragraph specifically, since the claimed invention is not supported for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Molecular Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F. 2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

10. Claims 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al, *Infect Immun.* 1982 September; 37 (3): 1209–1217.

Claims have been discussed supra in paragraph # 7.

Buckley et al disclose isolated nucleic acid, DNA (see abstract) from *C.albicans* cultures that were grown in the presence of [¹⁴C] uracil for at least six mass doublings (0.5, uCi/ml with 50 ug/ml of carrier uraci). Samples (0.5 ml) were precipitated in 5 ml of 10% trichloroacetic acid and were extracted with alkali by the method of Hatzfield .The residue from alkali treatment could be solubilized totally by hydrolysis in 10% trichloroacetic acid. (Page 1210, left column, last paragraph) Thus the solubilized sample contains isolated nucleic acid, which inherently

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encodes a fungal antigen having the recited properties. Characteristics such as molecular weight, the partial amino acid sequence are inherent in the preparation of isolated DNA extract, such a DNA would hybridize to isolated nucleic acid as claimed in claim 6. Thus the prior art anticipated the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

13. Claims 4 and 6 are rejected under 35 U.S.C. 102 (a) as being anticipated by Rhei et al Database GenEmbl, Acession number AF031478 (*Biochim. Biophys. Acta* 1426 (3), 409-419 (1999).

Claims have been discussed supra in paragraph # 7.

Rhie et al 1999 discloses an isolated nucleic acid molecule (see page 412 in *Biochim. Biophys. Acta* 1999) encoding a fungal antigen (see figure 5 in *Biochim. Biophys. Acta* 1999) from *Candida albicans* and is shown below.

AF031478 1859 bp DNA linear PLN 13-JAN-2000

DEFINITION *Candida albicans* manganese-superoxide dismutase precursor (SOD2)
gene, complete cds.

ACCESSION AF031478

VERSION AF031478.1 GI:2623884

KEYWORDS.

SOURCE *Candida albicans*

ORGANISM *Candida albicans*

Eukaryota; Fungi; Ascomycota; Saccharomycotina; Saccharomycetes;
Saccharomycetales; mitosporic Saccharomycetales; *Candida*.

REFERENCE 1 (bases 1 to 1859)

AUTHORS Rhie,G.E., Hwang,C.S., Brady,M.J., Kim,S.T., Kim,Y.R., Huh,W.K.,

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Baek,Y.U., Lee,B.H., Lee,J.S. and Kang,S.O.

TITLE Manganese-containing superoxide dismutase and its gene from *Candida albicans*

JOURNAL Biochim. Biophys. Acta 1426 (3), 409-419 (1999)

MEDLINE 99177423PUBMED 10076057

REFERENCE 2 (bases 1 to 1859)

AUTHORS Kang,S.O. and Rhie,G.

TITLE Direct Submission

JOURNAL Submitted (26-OCT-1997) Microbiology, Seoul National University,
Shinlim-dong, Kwanak-gu, Seoul 151-742, Republic of Korea

FEATURES Location/Qualifiers

source 1..1859

/organism="Candida albicans"

/mol_type="genomic DNA"

/db_xref="taxon:5476"

gene 848..1552

/gene="SOD2"

CDS 848..1552

/gene="SOD2"

/note="Mn-SOD"

/codon_start=1

/transl_table=12

/product="manganese-superoxide dismutase precursor"

/protein_id="AAB86583.1"

/db_xref="GI:2623885"

/translation="MFSIRSSSRVLLKASSATTRATLNAAASKTFTRSKYSLPELDYE

FSATEPYISGQINEIHYTKHHQTYVNNLNASIEQAVEAKSKGEVKKLVALEKAINFNG

GGYLNHCLWWKNLAPVSQGGGQPPSEDSKLGKQIVKQFGSLDKLIEITNGKLAGIQGS

GWAFIVKNKANGDTIDVITTANQDVTDPNLVPLIAIDAWEHAYYLQYQNVKADYFKN

LWHVINWKEAERRFEF"

sig_peptide 848..949

/gene="SOD2"

mat_peptide 950..1549

/gene="SOD2"

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/product="manganese-superoxide dismutase"

ORIGIN

1 tagcaagaac ttagcgcaa taccggacg ttataaaaa ggctgtcaaa ggggtggaac
61 catccacaat cgttacttat ttgtcagtg tgacacatat tgtctccaa tgttacgata
121 tttatgggt ttctggtaa gaaaaggatg tgccattgc aagattggct ttatatgaag
181 ctgctagaca agttataaat aacggtatga cctgttagg ttgactcca gttaatcgt
241 tgtaaaaaaa aaaaagataa tgtgtataga ttggtagcta ccaaatagac ataaattcg
301 gtccgattt aaggaaaatg gaaagattat gattttttt cgccatctct gtgtgattc
361 tcacacacca atcaaattg caataaatat gacagaataa aacggcaaag tctagttga
421 aatactgtat ttctctgtaa tcttgagtc tgatatacaa actaatcaat tggcagacat
481 tcaacgatag cgctacatat agattaatca ccagtttatg atagtaaca catgaaaag
541 ttacacataa taattgctta caaatgaaa cttaaattgt ggaactgtc gtgcacgtt
601 gtcttgattg ctccgaatc ccggtcttt tttttttt ttgggggtgt ctctttaat
661 tccgtgaaa ttaattatc aatctgttc cttagttgt ggtcttcaa atcaatctg
721 taatagtaga tttatttt tcaaaagtaa ttccacaatt tttttttt gctttcttc
781 ttctctttt ttttatatc ttttttact tcaattgaca taaagacaa ttgtactata
841 attaacaatg tttctatca gatcatcatc tcgtgttta ttaaaggctt ctccgcaac
901 caccgtgct acttgaacg ccgtgcttc caagacttc actagatcta aatatagtt
961 accagaattg gactatgaat tctccgtac tgaaccatac atttctggc aaataaacga
1021 aattcactac actaaacatc accaaactta tgtaacaac cttaatgctt caattgaaca
1081 agccgttgaa gccaaatcta aaggatgaat taaaaaattg gttgccttag aaaaagccat
1141 caatttcaac ggtgggtgtt acctcaatca ttgttgttg ttgaaaaact tggctcctgt
1201 ctctcaagg ggtggtaac caccaagtga agattccaaa ttaggtaaac aaatcgtaa
1261 acaatttgtt tcttggata aattgattga aatcaccaat ggcaaattgg ctggtattca
1321 aggttctgga tgggctttta ttgtaaaaa caaagccaat ggtgatacta ttgatgtcat
1381 caccactgct aaccaagata ctgttactga tccaaacttg gtccattga ttgctattga
1441 tgcttgggaa catgcttatt attgcaata ccaaatgtt aaagctgatt actcaagaa
1501 cctttggcat gttatcaact ggaaggaagc tgaaagaaga ttgaatttt aagtactgg
1561 aaaaagtca agtacatatt taaatccaat ataagaaaat aaaagagtta ctccgatag
1621 tgctgattt gcagtttaatt attcccat ttatataga taaatgca agaatatatt
1681 cctgattgtg acaaaaaaag gatagcgtt gatctgtagt tgggctaaaa tggaaattgg
1741 tgtatacagt tttgatttc aaaaccacca agctcacatt ctgatataa gattataaa
1801 atcgaataat atgcacatt gggaacctg tagggtttct tgaaatagg atcaagctt

The isolated nucleic acid molecule encodes a fungal antigen comprising the partial amino acid

sequence SEQ.ID.NO: 2 (see the sequence alignment Qy is the claimed SEQ.ID.NO: 2 and Db

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is the disclosed prior art sequence) and is 100% identical to the claimed nucleic acid encoding a fungal antigen comprising an antigenic protein comprising the partial amino acid sequence,

SEQ.ID.NO: 2 KYSLPELDYEFSAATEPYISGQINEIXYT.

Database : GenEmbl:

Alignment Scores:

Pred. No.:	2.1e-15	Length:	1859
Score:	141.00	Matches:	27
Percent Similarity:	96.43%	Conservative:	0
Best Local Similarity:	96.43%	Mismatches:	1
Query Match:	97.24%	Indels:	0
DB:	8	Gaps:	0

US-09-987-190-2 (1-30) x AF031478 (1-1859)

```

Qy          1 LysTyrSerLeuProGluLeuAspTyrGluPheSerAlaThrGluProTyrIleSerGly 20
              |||
Db          950 AAATATAGTTTACCAGAATTGGACTATGAATTCTCCGCTACTGAACCATACATTTCTGGT
1009

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Qy          21 GlnIleAsnGluIle***TyrThr 28
              |||
Db          1010 CAAATAAACGAAATTCACTACACT 1033

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As this protein comprises more than 6 amino acids it is an antigenic protein because peptides having 5-6 amino acids induce an immune response and are well accepted as antigens in the art of immunology. As this protein is isolated from fungus *Candida albicans*, the properties of a fungal antigen such as allergen activity are considered as an inherent property of the disclosed antigen. The N-terminal amino acid sequence alignment showed (see the sequence alignment) that the claimed protein encoded by nucleic acid and the prior art nucleic acid encoding the protein are identical. The gene *sod2* encoding manganese-containing super oxide dismutase has been cloned using a product obtained from polymerase chain reaction. Sequence analysis of the *sod2* predicted a manganese-containing super oxide dismutase that contains 234 amino acid residues with a molecular mass of 26173 daltons, and thus read on the claimed invention. The deduced N-terminal 34 amino acid residues serve as a signal peptide for mitochondrial

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translocation. Northern analysis with a probe derived from the cloned *sod2* revealed a 0.94-kb band, which corresponds approximately to the expected size of mRNA deduced from *sod2* and is expected to hybridize to the claimed nucleic acid. Thus the disclosed nucleic acid sequence read on claim 6 because it contains a partial amino acid sequence that is 100% identical to the partial amino acid sequence of the claimed protein and is encoded by the nucleic acid. The disclosed nucleic acid is 100% identical to the nucleic acid sequence of the claimed isolated nucleic acid and therefore would hybridize to the claimed nucleic acid as recited in claim 6. Further the nucleic acid is originated from genus *Candida*. The prior art anticipated the claimed invention.

16. Claims 4 and 6 are rejected under 35 U.S.C. 102 (e) as being anticipated by Weinstock et al U.S. Patent 6,747,137.

Claims have been discussed supra in paragraph # 7.

Weinstock et al disclose an isolated nucleic acid molecule (SEQ.ID.NO:3165 in patent) encoding a *Candida* fungal antigen (see SEQ.ID.NO: 17718 in the Patent). The disclosed protein comprises the partial amino acid sequence SEQ.ID.NO: 2 and is 100% identical to the protein encoded by the claimed nucleic acid as shown below (Qy is the partial amino acid sequence of SEQ.ID.NO: 2 and Db is the prior art nucleic acid, SEQ.ID.NO: 3615) in the sequence alignment.

```
US-09-248-796A-3615
; Sequence 3615, Application US/09248796A, U.S. Patent 6747137
; GENERAL INFORMATION:
; APPLICANT: Keith Weinstock et al
; TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO
CANDIDA ALBICANS
; TITLE OF INVENTION: FOR DIAGNOSTICS AND THERAPEUTICS
; FILE REFERENCE: 107196.132
; CURRENT APPLICATION NUMBER: US/09/248,796A
; CURRENT FILING DATE: 1999-02-12
; PRIOR APPLICATION NUMBER: US 60/074,725
; PRIOR FILING DATE: 1998-02-13
; PRIOR APPLICATION NUMBER: US 60/096,409
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; PRIOR FILING DATE: 1998-08-13
 ; NUMBER OF SEQ ID NOS: 28208
 ; SEQ ID NO 3615
 ; LENGTH: 687
 ; TYPE: DNA
 ; ORGANISM: Candida albicans
 US-09-248-796A-3615

Alignment Scores:

Pred. No.:	1.91e-16	Length:	687
Score:	141.00	Matches:	27
Percent Similarity:	96.43%	Conservative:	0
Best Local Similarity:	96.43%	Mismatches:	1
Query Match:	97.24%	Indels:	0
DB:	5	Gaps:	0

US-09-987-190-2 (1-30) x US-09-248-796A-3615 (1-687)

```

Qy      1 LysTyrSerLeuProGluLeuAspTyrGluPheSerAlaThrGluProTyrIleSerGly 20
          ||||||||||||||||||||||||||||||||||||||||||||
Db      109 AAATATAGTTTACCAGAATTGGACTATGAATTCTCCGCTACTGAACCATACATTTCTGGT
168

Qy      21 GlnIleAsnGluIle***TyrThr 28
          ||||||||||||| |||||
Db      169 CAAATAAACGAAATTCACTACACT 192

```

As this protein comprises more than 6 amino acids it is an antigenic protein because peptides having 5-6 amino acids induce an immune response and are well accepted as antigens in the art of immunology. The disclosed protein is isolated from fungus *Candida albicans*, therefore, the properties of a fungal antigen such as allergen activity are considered as an inherent property of the disclosed antigen. The N-terminal amino acid sequence alignment showed (see the sequence alignment) that the claimed protein encoded by nucleic acid and the prior art nucleic acid encoding the protein are identical.

The prior art nucleic acid sequence encoding a fungal antigen reads on claimed protein having a molecular weight of about 25000 daltons because the disclosed protein has 229 amino acids (each amino acid is approximately 110 daltons). The disclosed nucleic acid is 100% identical to the nucleic acid sequence of the claimed isolated nucleic acid and therefore

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would hybridize to the claimed nucleic acid as recited in claim 6. Further the nucleic acid is originated from genus *Candida*. The prior art anticipated the claimed invention.

Remarks

17. No claims are allowed.

Conclusion

18. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

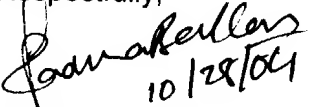
19. Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Respectfully,

Handwritten signature of Padma Baskar in cursive script, with the date 10/28/04 written below it.

Padma Baskar Ph.D.